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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|-------------|----------------------|---------------------|----------------------------------|
| 10/822,370 | 04/12/2004 | John Shanklin | BSA 04-11 | 2864 |
| 26302 | 7590 | 10/26/2006 | EXAMINER | |
| BROOKHAVEN SCIENCE ASSOCIATES/ BROOKHAVEN NATIONAL LABORATORY BLDG. 475D - P.O. BOX 5000 UPTON, NY 11973 | | | | SAIDHA, TEKCHAND |
| | | | | ART UNIT 1652 PAPER NUMBER |

DATE MAILED: 10/26/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

| Office Action Summary | Application No. | Applicant(s) |
|------------------------------|------------------------|---------------------|
| | 10/822,370 | SHANKLIN ET AL. |
| Examiner | Art Unit | |
| Tekchand Saidha | 1652 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) Responsive to communication(s) filed on 18 September 2006.

2a) This action is **FINAL**. 2b) This action is non-final.

3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4) Claim(s) 1-53 is/are pending in the application.
4a) Of the above claim(s) 18-53 is/are withdrawn from consideration.

5) Claim(s) _____ is/are allowed.

6) Claim(s) 1-10 is/are rejected.

7) Claim(s) 11-17 is/are objected to.

8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9) The specification is objected to by the Examiner.

10) The drawing(s) filed on 12 April 2004 is/are: a) accepted or b) objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) All b) Some * c) None of:
1. Certified copies of the priority documents have been received.
2. Certified copies of the priority documents have been received in Application No. _____.
3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) Notice of References Cited (PTO-892)
2) Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____
4) Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
5) Notice of Informal Patent Application
6) Other: _____

DETAILED ACTION

1. Applicant's election without traverse of Group I, claims 1-17, in the reply filed on September 18, 2006 is acknowledged.
2. Claims 18-53 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on September 18, 2006.
3. Claims 1-17 are under consideration in this Office Action.
4. **Claim Rejections - 35 USC § 112** (second paragraph)

Claims 1-17 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 1-17, either independently or in a dependent manner recite the phrase 'residue homologous to'; for a specific example, in claim 1 (a) Ala, Thr, Ser, or Ile at the residue homologous to Met 114 of SEQ ID NO: 1.'

The claims are indefinite and unclear because residues Ala, Thr, Ser, or Ile are being substituted for Met 114 of SEQ ID NO: 1.

Amending the claims to delete the expression 'residue homologous to' throughout. As an example, claim 1 may be rewritten as follows:

1. A DNA expression construct comprising ~~in-expressible form~~, a nucleic acid sequence which encodes a mutant Δ⁹-18:0-ACP desaturase having one or more amino acid substitutions selected from the group consisting of and wherein :
 - a) Ala, Thr, Ser, or Ile is substituted for Met 114 of SEQ ID NO: 1;
 - b) Arg is substituted for Thr 117 of SEQ ID NO: 1;
 - c) Gly, Ala or Cys is substituted for Leu of 118 of SEQ ID NO: 1;

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- d) Val or Leu is substituted for Pro 179 of SEQ ID NO: 1;
- e) Val, Ser, Phe or Trp is substituted for Thr 181 of SEQ ID NO: 1; and
- f) Leu or Thr is substituted for Gly 188 of SEQ ID NO: 1.

Other claims may similarly be amended to overcome this rejection

The phrase 'in expressible form' is redundant and confusing because if it is a DNA expression construct it is capable of expression. Deletion of 'in expressible form' is suggested to overcome this rejection.

5. Claims 11-17 are objected to under 37 CFR 1.75(c) as being in improper form because a multiple dependent claim cannot depend on another multiple dependent claim. See MPEP § 608.01(n). Multiple dependent claims shall not serve as a basis for any other multiple dependent claim. Accordingly, the claims 11-17 are not been further treated on the merits.

6. Accordingly claims 1-10 are under consideration for the remainder of this Office Action.

7. ***Claim Rejections - 35 U.S.C. § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that

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was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cahoon et al. [PNAS 94: 4872-4877, May 1997, Reference 1]. Cahoon et al. teach castor mutants or modified Δ^9 - 18:0-ACP desaturase, the encoding DNA and the crystallographic model of the active sites and variants or mutants. Characterization of specific mutants at positions 114, 117, 118, 179, 181 & 188 are also taught (see the entire document, especially abstract, Fig. 3, and page 4875-column 2, materials and methods). The reference also teaches specific positions which can be replaced by any amino acid or which can be used for making two or more amino acid substitutions in the castor Δ^9 - 18:0-ACP desaturase and having increased activity towards fatty acids having fewer than 18 carbon [see column 5, lines 50-60].

Cahoon et al. do not teach the specifically claimed substitution(s).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to substitute parent amino acid at positions 114, 117, 118, 179, 181 & 188 with any of the remaining 19 amino acids, make DNA constructs comprising the mutated DNA and suitably express in a host cell, and do so with a reasonable expectation of success. One of ordinary skill in the art would have been motivated to do so in view of the potential use of desaturase mutants in the production low calorie margarine and as a precursor of adipic acid for the manufacture of nylon, as suggested in the teachings of the reference (see page 4876, column 2; Fig. 4 & 5). Thus, the claimed invention was within the ordinary skill in the art to

make and use at the time was made and was as a whole, *prima facie* obvious.

8.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321© may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b). Claims 1-10 are rejected under the judicially created doctrine of double patenting over claims 1-9 of U. S. Patent No. 5,705,391 and/or Claims 33-38 & 51-58 of U. S. Patent No. 6,100,091 since the claims, if allowed, would improperly extend the "right to exclude" already granted in the patent. These are two separate DP rejections combined into a single paragraph for convenience.

The subject matter claimed in the instant application is fully disclosed in the patent and is covered by the patent since

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the patent and the application are claiming common subject matter, as follows:

Cahoon et al. (U. S. Patent No. 5,705,391) teach mutants or modified Δ^9 -18:0-ACP desaturase (see claims 1-9) at the identified contact residues M114, L115, T117, L118, G188 & F189, and how these specific positions can be replaced by any other amino acid or which can be used for making two or more amino acid substitutions in the castor Δ^9 -18:0-ACP desaturase and having increased activity towards fatty acids having fewer than 18 carbon. The instant claims are drawn to specific amino acid substitutions at the positions indicated which are encompassed by the patented claims. The claims to specific mutants in the instant application are narrower (species) than the broader (genus) claims of the cited patent. Since a species anticipates a genus; and a genus make species claims obvious, the instant claims are obvious over the claims of U. S. Patent No. 5,705,391.

For the same reasons as described in the previous paragraph, the instant claims are obvious over claims 33-38 & 51-58 of U. S. Patent No. 6,100,091

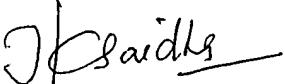
9. No claim is allowed.

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Tekchand Saidha whose telephone number is (571) 272 0940. The examiner can normally be reached on 8.30 am - 5.00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapu Achutamurthy can be reached on (571) 272 0928. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.


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October 23, 2006